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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,352	01/21/2000	JAAP GOUDSMIT	T/97300 US	6213

7590 11/19/2003

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/463,352	GOUDSMIT ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 17 September 2003 has been entered.

Response to Amendment

2. Acknowledgement is made of applicant having filed an amendment on 17 September 2003. It is further noted that the amendment does not account for al claims that are or have pended in the instant application. In particular, the claims do not account for claim 10, which was canceled via the preliminary amendment of 21 January 2000.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

For convenience, claim 13 is reproduced below.

> 13. (currently amended) A pair of oligonucleotide primers consisting of:
>
> (i) a first hybridizing oligonucleotide selected from the group consisting of:
>
> SEQ ID 1: G GGC GCC ACT GCT AGA GA;
>
> SEQ ID 2: G TTC GGG CGC CAC TGC TAG A; [and]
>
> SEQ ID 3: CGG GCG CCA CTG CTA; and
>
> SEQ ID 9: aat tct aat acg act cac tat agg gAG AGG GGC GCC ACT GCT AGA GA; and
>
> (ii) a second hybridizing oligonucleotide selected from the group consisting of:
>
> SEQ ID 4: CTG CTT AAA GCC TCA ATA AA; and
>
> SEQ ID 5: CTC AAT AAA GCT TGC CTT GA; ~~and~~
>
> ~~SEQ ID 12: GAT GCA TGC TCA ATA AAG CTT GCC TGG AGT.~~

Claim 13 has been interpreted as encompassing combining SEQ ID NO:9 with either SEQ ID NO: 4 or 5. A review of the disclosure find were at page 7 SEQ ID NO: 1-3 could be combined with SEQ ID NO: 4, 5, or 12. Page 8 does teach that SEQ ID NO:9 can be combined with SEQ

ID NOP:5, however, no support for combining SEQ ID NO:9 with that of SEQ ID NO: 4 can be found.

At page 5 of the response of 17 September 2003 applicant asserts:

> Support for these claim amendments and new claims is found in the language of the original claims and throughout the specification, as set forth below.

A review of the specification and response fails to find where applicant had contemplated this combination of primers at the time of filing. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

4. Accordingly, and in the absence of convincing evidence to the contrary, the amendment to claim 13 effectively introduces new matter into said claim 13 and into claims 14-18 that depend therefrom.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-9, 11-14, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montagnier t al. (US Patent 5,221,610), in view of Backus et al., (US Patent 6,001,558) and Research Genetics.

8. Montagnier et al., column 19, third paragraph, bridging to column 20, disclose primers for detecting HIV-1 and methods of doing same. At column 19, last paragraph, bridging to column 20, first two lines, Montagnier et al., teach explicitly of directing primers to conserved regions and specifically teaches that one such region of conserved sequences is found in the long terminal repeat, or LTR. It is noted that the LTR is the very region from which applicant has selected the instantly claimed primers/probes; see the response of 26 December 2000, page 7, lines 13-15, wherein is stated:

> The primers of the present invention are not from the GAG region, but instead are from the long terminal repeat (LTR) of HIV-1."

It is abundantly clear that Montagnier et al., are directing the public to this very region for the selection of primers and probes. Furthermore, they provide motivation in selecting sequences

that allow for the detection of multiple isolates when they teach that the LTR is "highly conserved."

9. Montagnier et al., column 20, second full paragraph, states that by using PCR, which they consider to be more sensitive, one would be able to eliminate viral-isolation assays.

10. While Montagnier et al., do teach of conducting PCR on the LTR region of HIV, they do not teach explicitly of applicant's sequences.

11. Backus et al., disclose at column 6, fist paragraph, that primers can range in size or length from 12 to 60 nucleotides and that a preferable range is from 16 to 40 nucleotides and that a more preferable range is from 18 to 35 nucleotides. It is noted that applicant's SEQ ID NO: 1 comprises 18 nucleotides; SEQ ID NO: 2 comprises 20 nucleotides; SEQ ID NO: 4 and 5 comprises 20 nucleotides each; and SEQ ID NO: 12 comprises 30 nucleotides.

12. As seen in column 11, oligonucleotides corresponding to SEQ ID NO: 2, 4, and 24 comprise the nucleotide sequence as found in applicants oligonucleotides represented by SEQ ID NO: 1, 2, 4, 5.

13. To the extent that claims 13, 14, 16 and 18 are rendered obvious by the prior art, it is noted that claim 13 allows for the combination of SEQ ID NO: 1, 2, or 3 with that of SEQ ID NO: 4 or 5. As shown above, the Backus et al., teaches explicitly of using primers that correspond to applicants' SEQ ID NO: 1, 2, 4 and 5.

14. Research Genetics, through their advertisement, disclose for sale software that allows the ordinary artisan to set parameters whereby the software will automatically screen all possible sequence comparisons and provide a listing of those primers that meet the established criteria. As seen in the publication, such parameters to be employed in the selection of primer and probe

sequences include desired specificity, length, GC content, secondary structure characteristics, etc. Accordingly, the designing of a sequence over that of another, especially when the very source is known and the prior art directs one to use such a sequence, speaks of routine optimization. It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955):

> Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. In re Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52; In re Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. In re Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; In re Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. In re Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; In re Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; In re Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added)

15. It would have been obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to have used the software of Research Genetics with the teachings of Backus et al., and Montagnier et al., so to select primers and probes form the LTR region of HIV-1 where such sequences are identified through the use of the commercially available sequence screening software. As shown above, Backus et al., disclose not only the sequences but directs the public to preferred sizes of primers. It is noted with particularity that the sizes of

primers disclosed by Backus et al., corresponds to that claimed instantly. And with the public being armed with the sequences, preferred size ranges and software that will perform the necessary calculations and produce nucleotide sequences that meet such criteria, the selection of primer sequences that have such features would have been profoundly obvious. And given the art-recognized sensitivity of PCR and the interests that abounds in HIV-related diagnostics, the ordinary artisan would have been highly motivated as well. Additionally, said ordinary artisan would have been motivated to have configured the primer pair(s) in a kit format as such would have been an obvious commercial expedience, requiring little if any additional research and development.

Response to argument

16. At page 8, bridging to page 9 of the response received 17 September 2003, argument is advanced that the patent of Backus et al., is not available prior art as a result of the submission of a declaration under 37 CFR 1.131. Applicant acknowledges that the declaration is unsigned and that a signed version will be submitted shortly.

17. A review of the contents of the file fail to locate a signed version of the declaration filed under 37 CFR 1.131. Accordingly, the unsigned declaration has been considered without effect towards the withdrawal of the rejection.

18. At page 10, last paragraph, applicant requests the Office to provide "a detailed explanation regarding why the arguments presented by applicants fails to demonstrate why the use of the Research Genetics software program does not render the claimed invention obvious." Whether intentional or not, it appears that applicant has conceded that the prior art does render

the claimed invention obvious and is seeking the Office to make the case that the invention is not rendered obvious. Applicant's arguments have been fully considered. As an initial matter, the Office declines applicant's offer for the Office to prove the null hypothesis and secondly, the Office agrees with applicant that the combination of prior art, and especially the teaching of Research Genetics, does render the claimed invention obvious.

19. To the extent that argument is advanced at pages 9-11 that the rejection cannot be maintained in the absence of Backus et al., it is noted with particularity that applicant has not removed the Backus et al., document as available prior art.

Conclusion

20. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

21. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

24. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
14 November 2003